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PRELIMINARY RESULTS FROM A PHASE II STUDY OF LENALIDOMIDE MONOTHERAPY IN RELAPSED/REFRACTORY AGGRESSIVE NON-HODGKINS LYMPHOMA

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Background. Lenalidomide (Revlimid®) is an immunomodulatory drug of the IMiD class, recently approved in the US for myelodysplastic syndromes associated with a deletion 5q[31] cytogenetic abnormality that also has activity in multiple myeloma, chronic lymphocytic leukemia and cutaneous T-cell lymphoma. Thalidomide, a less potent IMiD, has activity in non-Hodgkin's lymphoma as both monotherapy and in combination with rituximab. *Aim.* To assess the safety and efficacy of lenalidomide monotherapy in subjects with relapsed/refractory aggressive non-Hodgkin's lymphoma (NHL). *Methods.* Subjects with relapsed/refractory aggressive NHL following > 1 prior treatment regimen with measurable disease are eligible. Subjects receive 25 mg lenalidomide orally once daily on Days 1-21 every 28 days and continue therapy for 52 weeks as tolerated or until disease progression. Response and progression are evaluated using the IWLRC methodology. *Results.* 19 subjects of a planned 40 were enrolled of which eight subjects are currently evaluable for tumor response and safety. The median age of the 8 evaluable subjects is 66 (45-80) and 5 are female. Histology is diffuse large cell lymphoma (n=7) and follicular center lymphoma grade 3 (n=1). Median time from diagnosis to lenalidomide monotherapy is 2.3 (1-6) years and median number of prior treatment regimens per subject is 3 (1-6). Median duration of follow-up is 3.5 (1-5) months. Three of the eight subjects exhibited a PR with decreases in their tumor burden of 93%, 79% and 52%. Two subjects had stable disease and three, disease progression. Grade 3 or 4 hematological adverse events (neutropenia, thrombocytopenia, anemia) occurred in five subjects including one febrile neutropenia and one of the five also exhibited Grade 3 sub-acute autoimmune hemolysis and Grade 4 general malaise. *Conclusion.* Preliminary data for lenalidomide monotherapy in relapsed/refractory aggressive NHL are encouraging.

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RITUXIMAB SIGNIFICANLY IMPROVES THE OUTCOME OF YOUNG POOR RISK PATIENTS WITH DIFFUSE LARGE B-CELL LYMPHOMA - ON BEHALF OF CZECH LYMPHOMA STUDY GROUP

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Background. There is a robust evidence of significant patients outcome improvement by adding rituximab (R) to chemotherapy (CHT) in patients (pts) with DLBCL who are older (Coiffier, 2002) or younger with good risk profile (Pfreundschuh, 2004). There is lack of evidence of benefit R-CHT over CHT for younger pts with DLBCL and poor risk profile according to IPI and moreover the benefit of combination of rituximab and primary high dose therapy (HDT) with autologous stem cell transplantation (ASCT) is unclear. *Aim.*To perform the retrospective analysis of pts with DLBCL and intermedate-high (IH) or high (H) aaIPI, younger than 60y registered in CLSG registry since Jan 1999 till Dec 2004 and treated with anthracyclin containing chemotherapy and to compare the chemotherapy only treated group (CHT) vs rituximab and CHT (R-CHT) treated group. *Methods.* Altogether 178 eligible pts were identified, 118 (66.3%) with CHT nad 60 (33.7) with R-CHT. The median of rituximab infusions was 6 (4-8) and 5 pts with less than 4 cycles of R were counted as CHT only pts. There were no significance difference in CHT vs R-CHT in terms of age (median 47 in both), clinical stage (advanced 92.4% vs 95%), elevated LDH (91.5% vs 89.8%), H risk aaIPI (42.4% vs 35%), radiotherapy as part of the induction (41% vs 54.7%). The only difference between groups was in the number of pts exposed to HDT with ASCT (38.5% vs 60%, p=0.01). The median follow up in CHT group was 4.6 years vs 2.4 in R-CHT group. The 3 years probability of overall survival - OS - and event free survival *EFS* (time from dg to progression/relaps or death, whatever occured earlier, in all pts) were considered as primary endpoints. Epiinfo and GraphPad programs were used for analysis (ANOVA, Wilcoxon test and log rang tests were used). *Results.* The probability of EFS and OS in the whole group was 52% and 61% resp. The probability of EFS in CHT vs R-CHT was 40.1% vs 74.8% (p<0.0001) resp. and OS was 50.8% vs 83.2% (p<0.0001). Because of inbalance in the HDT with ASCT, the subanalyses were performed. The comparison of subgroup of pts who all were treated with HDT as part of the induction according to R administration (CHT vs R-CHT) reveals the significant differences for EFS: 55.5% vs 88.8% (p<0.005) as well as for OS: 61.4 vs 91.4 (p<0.01). There were also singinficant differences between CHT vs R-CHT groups when pts without primary HDT were analyzed: EFS: 32.9% vs 50.9% (p<0.02) and OS: 45.0% vs 67.7% (p<0.01). There was found no difference between intermediate-high and high subgroups. *Conclusion.* This retrospective analysis suggests: Young pts with DLBCL and poor risk IPI have significantly better outcome if they are treated with rituximab containing chemotherapy. Moreover the R-CHT significantly improves the outcome of patients who are designated to HDT with ASCT in comparison of pts who are treated with CHT without R followed by HDT with ASCT.

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WHATS THE SIGNIFICANCE OF FDG-PET/CT SCAN AT DIAGNOSIS OF NON HODGKIN LYMPHOMAS?

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Background. Correct staging is important for the appropriate treatment in lymphoma patients. Most cancers, including lymphomas, metabolize glucose at abnormally high rate and so FDG-PET/CT is an important tool in the evaluation of patients with lymphoma. Many authors in these last years have shown the importance of FDG-PET/CT analysis at diagnosis of lymphomas and the differences according to histologic subtypes. *Aims.* The IIL (Italian Lymphoma Intergroup) evaluated:1) the role of FDG-PET/CT versus CT scanning in the staging of Non-Hodgkin's lymphoma, 2) the significance of FDG-PET/CT according to histologic subtypes, 3) the ability of FDG-PET/CT in showing extranodal localizations. *Methods.* We have retrospectively analysed at diagnosis 105 patients (pts) (53 male, 52 female) with both FDG-PET/CT and conventional CT scanning. The histologic subtypes were: diffuse, large B-cell lymphoma (LBCL) 49 pts (47%), follicular lymphoma (FL) 37 pts (35%), marginal zone lymphoma (MZL) 7 pts (6%), mantle cell lymphoma (MCL) 4 pts (4%), Burkitt and Burkitt-like lymphoma (BL) 3 pts (3%), primitive mediastinal B-cell lymphoma 2 pts (2%), other lymphomas (small lymphocytic, peripheral T-cell, extranodal) 3 pts (3%). The PET/CT scans (GE, Discovery, LS) were performed 60 min. after the i.v. injection of 18F-FDG (5.5 MBq/kg) with a whole-body acquisition with a field of view extending from the head to the upper part of the thighs. All patients fasted for at least 8 hours prior to FDG injection and had a glucose level < 120 mg/dL. *Results.* We have evaluated nodal (18) and extranodal (12) stations. Considering all cases, the agreement between FDG-PET/CT and CT scanning was 89% in nodal stations and 95% in extranodal ones, while discordance was 9% (7% toward PET/CT and 2% toward CT), and 5% (4% toward PET/CT and 1% toward CT) respectively. The percentage was similar in all the different histologic subtypes. The extranodal localizations in which there were more discordances were spleen (7 pts), liver (6 pts), and bones (17 pts. FDG-PET/CT upstaged 27/105 pts (26%) and for 17% of pts the upstaging modified therapy (0 → III-IV in 4 pts (4%), I→ III-IV in 3 pts (3%), II → III-IV in 10 pts (10%). The FDG-PET/CT downstaged only 9/105 pts (9%): II→ I in 1 pts (1%), III-IV → II in 5 pts (5%), I → 0 3 pts (3%). *Conclusions.* FDG-PET/CT and CT scanning are concordant, for nodal and extranodal localizations, in staging of Non-Hodgkin lymphomas. FDG-PET/CT shows more nodal localizations (7%) and extranodal localizations (4%) than CT scanning. There isn't s substantial difference in concordance between FDG-PET/CT and CT scanning according to the various histologic subtypes. It is important to have FDG-PET/CT baseline for early and late evaluation during and after therapy. FDG-PET/CT is essential for staging lymphomas also as exclusive method.